K002597

CardioNow

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9.0 510(k) Summary

Submitter

CardioNow, Inc.
543 Encinitas Boulevard Suite 109
Encinitas, CA 92024

Contact

Johnny Garza
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Device Name

Classification: Class II
Common/usual name: Cardiac Cath Image Acquisition system, a PACS (Picture Archive and Communications) device
Proprietary Name: CN Acquisition Station

Intended Use

The CN Acquisition System is intended to acquire images from a video signal in the cardiac catheterization laboratory in parallel with existing equipment and convert these images to a DICOM Format. The intent is to allow DICOM networks to obtain data from cardiac catheterization laboratories not having a DICOM output

Device Description

CardioNow's CN Acquisition Station acquires cardiac catheterization images in parallel with the existing equipment in the catheterization laboratory for the purpose of converting the images to a DICOM format to send to devices on a DICOM network.

Comparisons to Predicate Device

The substantial equivalent device is the Camtronics Video Plus Cardiac device, FDA 510 number K954150.

CardioNow

In reviewing the comparison between CardioNow's CN Acquisition Station and the predicate device, the following differences are noted. The Camtronics device offers angiography options for studies other than cardiac catheterization exams. The Camtronics device offers image display and processing options for use in the lab.

The CardioNow device is intended solely for cardiac catheterization laboratories and as such, does not offer an angiography option. The CardioNow device is an acquisition station only and does not provide a display option.

Conclusion

For the acquisition of images from the cardiac catheterization laboratory and the conversion of these images to the DICOM format for distribution over a network, the CardioNow CN acquisition system and the Camtronics system use similar techniques and have the same functions. Thus, for cardiac catheterization image acquisition and conversion to DICOM format, the CardioNow device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 7 2000

Johnny M. Garza
Director, Software Quality Assurance
CardioNow, Inc.
535 Encinitas Blvd. Suite 115
Encinitas, CA 92024

Re: K002597
CN Acquisition Station
Dated: August 15, 2000
Received: August 21, 2000
Regulatory class: II
21 CFR 892.2030/Procode: 90 LMA

Dear Mr. Garza:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002597

Device Name: CN Acquisition Station

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

Prescription Use

David A. Feigal (Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002597

(Posted July 1, 1998)